IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Schultz
App. No	:	10/773,756
Filed	:	February 6, 2004
For	:	DRUG FORMULATIONS FOR COATING MEDICAL DEVICES
Examiner	:	Carlos A. Azpuru
Art Unit	:	1615
Conf #	:	4024

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1/22/08
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Nathan S. Smith, Reg. No. 53,615

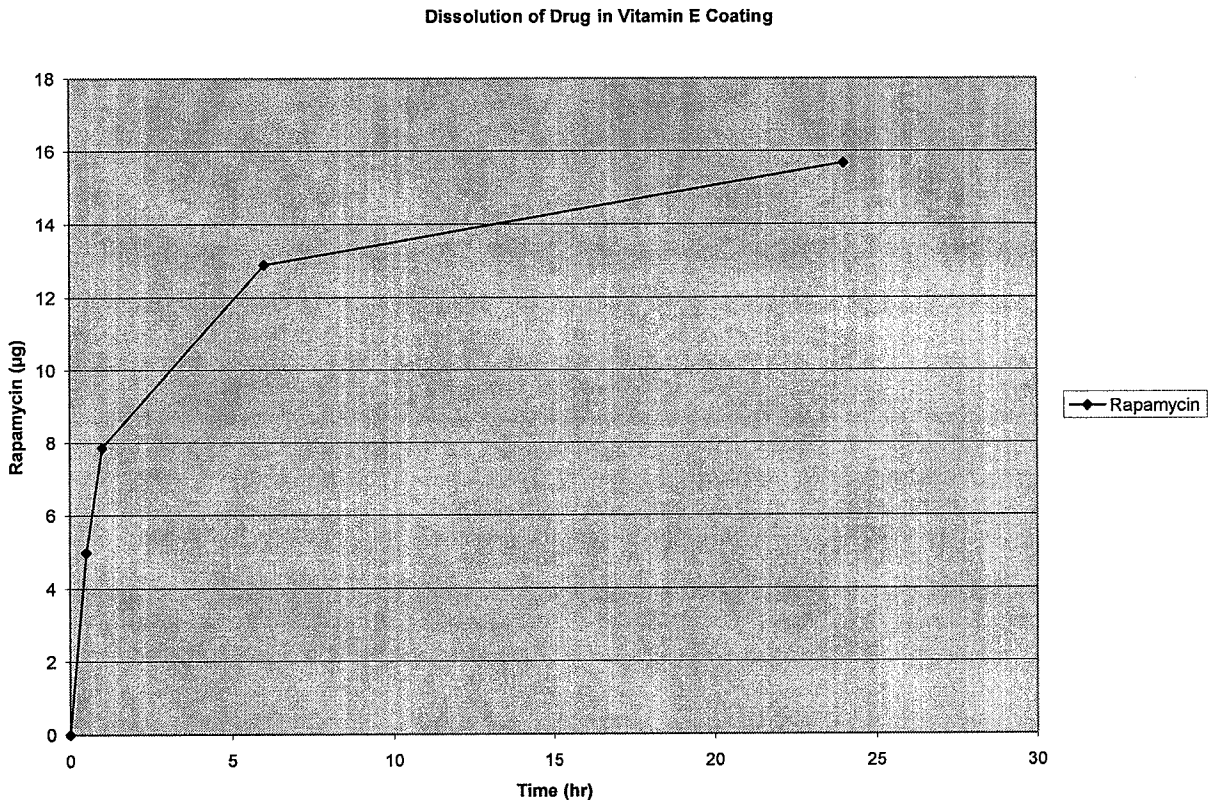
DECLARATION OF ROBERT SCHULTZ

I, Robert K. Schultz declare as follows:

1. I am President and COO of REVA Medical, Inc., a company involved in developing interventional medical devices with novel stent designs and biomaterials to improve the treatment of vascular disease. I obtained a Ph.D. in Pharmaceutics and a B.S. degree in Pharmacy from the University of Minnesota. Before joining REVA, I held the positions of Vice President of Research and Development and Vice President of Technology Strategy and Licensing for Dura Pharmaceuticals, and Research Specialist for 3M Pharmaceuticals. I have been working in the pharmaceutical and medical device industries for more than 27 years.

2. I am familiar with the prosecution of the present application, 10/773,756, which is directed to one of REVA's drug coating technologies; I am also the sole inventor of the present application. I understand that the pending claims stand rejected in part as allegedly lacking an enabling disclosure for coating formulations that comprise a genus of hydrophobic therapeutic agents. I also understand that I am making this Declaration to provide objective evidence that one skilled in the art would be enabled by the disclosure in the patent specification to make and use coating formulations comprising a hydrophobic therapeutic agent.

3. I instructed a technician at REVA to prepare a coating formulation as described in the patent specification by dissolving a hydrophobic therapeutic agent (other than C6-ceramide), in this case 15 mg rapamycin, in a mixture of a volatile solvent and a non-volatile oil-based solvent, in this case 100% HPLC grade ethanol and 10% Vitamin E, respectively. The final concentration of rapamycin was 0.5% w/w. Angioplasty balloons were inflated at 3 atm and then coated by emersion into the coating formulation. Ethanol was evaporated off of the coated balloon under N_2 for 1-2 minutes and the coating/drying step was repeated 5 times. Balloons were cut off of the catheters and placed in a test tube with 0.05% Tween and ascorbic acid and agitated at 80 rpm on a bench-top shaker at 37 C. Samples were taken at 0, 0.5, 1, 6 and 24 hours. The time course of rapamycin release was determined by HPLC. The results represent the average of duplicate determinations for each of two separate balloon samples; the time course of rapamycin dissolution from the balloon coating is illustrated in the Figure below.



4. The coating method was simple to carry out based on the disclosure in the patent specification, and the results summarized in the Figure demonstrate that the coating mixture

formulated using another hydrophobic drug was effective in coating a device, wherein the drug dissociated from the coated device in a predictable, time-dependent manner.

5. I declare that all statements made herein are true, and that all statements made upon information and belief are believed to be true, and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that willful, false statements may jeopardize the validity of the application, or any patent issuing thereon.

Dated: January 22, 2008 By: _____
Robert K. Schultz

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